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**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US) 371  
CONCERNING A FILING UNDER 35 U.S.C.**

ATTORNEY'S DOCKET NO.: **TIP-0058-USPCT**

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

**10/570228**

INTERNATIONAL APPLICATION NO.  
PCT/EP2004/052028

INTERNATIONAL FILING DATE  
September 3, 2004

**PRIORITY DATES CLAIMED**

September 3, 2003 (EP Appln. No.: 03103275.8),  
September 3, 2003 (US Provisional Appln. No. 60/499,771)  
September 8, 2003 (EP Appln. No.: 03103319.4)  
September 10, 2003 (EP Appln. No.: 03103335.0)  
October 2, 2003 (EP Appln. No.: 03103668.4)  
October 3, 2003 (US Provisional Appln. No.: 60/508,486)

TITLE OF INVENTION **COMBINATIONS OF A PYRIMIDINE CONTAINING NNRTI WITH RT INHIBITORS**

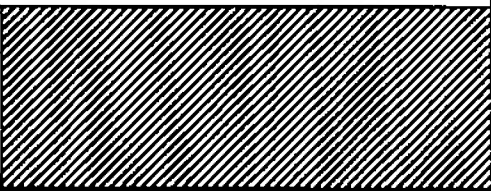
APPLICANT(S) FOR DO/EO/US : **Paul Stoffels**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

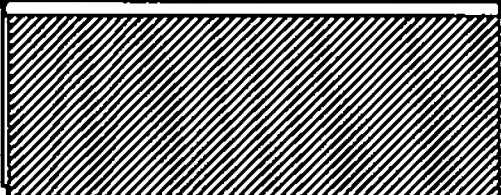
1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
  2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
  3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below
  4. ☒ The US has been elected (Article 31).
  5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
    - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
    - b. ☐ has been communicated by the International Bureau.
    - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
  6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
    - a. ☐ is attached hereto
    - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
  7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
    - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
    - b. ☐ have been communicated by the International Bureau.
    - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
    - d. ☒ have not been made and will not be made.
  8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
  9. ☒ One (1) Power of Attorney or Authorization of Agent of the inventor(s) (35 U.S.C. 371(c)(4)).
  10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).
- Items 11 to 20 below concern document(s) or information included:**
11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
  12. ☒ Two (2) assignment documents for recording. A separate cover sheet for each Assignment in compliance with 37 CFR 3.28 and 3.31 is included.
  13. ☒ A preliminary amendment.
  14. ☒ One (1) Certificate Under 37 CFR 3.73(b).
  15. ☒ One (1) Declaration of Inventorship.
  16. ☒ Other items or information: Express Mail Certification, Priority Document WO2005/021001 A1 (together with the International Search Report, Written Opinion of the ISA and PCT Request).

This collection of information is required by 37 CFR 1.414 AND 1.491-1.492. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing; and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

|  |              |   |            |  |                 |
|--|--------------|---|------------|--|-----------------|
| U.S. APPLICATION NO. <u>10/570228</u> (known as 37 CFR 1.5)  |              | INTERNATIONAL APPLICATION NO.<br>PCT/EP2004/052028                            |            | ATTORNEY'S DOCKET NUMBER<br>TIP-0058-USPCT   |                 |
| 21. <input checked="" type="checkbox"/> The following fees are submitted:<br><br>x a) Basic national fee .....\$300.00<br>X b) Examination fee.....\$200.00<br>X c) Search fee..... \$500.00<br><br>TOTAL OF ABOVE CALCULATIONS = \$ 1000.00                               |              |   |            | Applicant use  | Office use only |
|  |              |   |            | \$ 300.00  |                 |
|  |              |   |            | \$ 200.00  |                 |
|  |              |   |            | \$ 500.00  |                 |
|  |              |   |            | \$ 1,000.00  |                 |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. |              |   |            |  |                 |
| Total Sheets   | Extra sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE       |  |                 |
| - 100 =  | /50 =        |   | x \$250.00 | \$ 0.00  |                 |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).   |              |   |            | \$ 0.00  |                 |
| CLAIMS   | NUMBER FILED | NUMBER EXTRA  | RATE       |  |                 |
| Total claims   | 24 -20       | 4   | x \$50.00  | \$ 200.00  |                 |
| Independent claims   | 1 - 3        | 0   | x 200.00   | \$ 0.00  |                 |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable)  |              |   | + \$300.00 | \$ 0.00  |                 |
| TOTAL OF ABOVE CALCULATIONS =  |              |   |            | \$ 200.00  |                 |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2  |              |   |            | \$ 0.00  |                 |
| SUBTOTAL =   |              |   |            | \$ 1,200.00  |                 |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).  |              |   |            | \$ 0.00  |                 |
| TOTAL NATIONAL FEE =   |              |   |            | \$ 1,200.00  |                 |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +   |              |   |            | \$ 80.00   |                 |
| TOTAL FEES ENCLOSED =  |              |   |            | \$ 80.00   |                 |
| Amount to be refunded:   |              |   |            |   | \$              |
| Amount to be charged:  |              |   |            |  | \$ 1,280.00     |
| a. <input type="checkbox"/> A check in the amount of \$_____ to cover the above fees is enclosed.  |              |   |            |  |                 |
| b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>10-0750/TIP-0058-USPCT/LAD</u> in the amount of \$1,280.00 to cover the above fees.<br>A duplicate copy of this sheet is enclosed.  |              |   |            |  |                 |
| c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>10-0750/TIP-0058-USPCT/LAD</u> . A duplicate copy of this sheet is enclosed.         |              |   |            |  |                 |
| d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. <b>Credit Card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038.        |              |   |            |  |                 |
| <b>NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.</b>   |              |   |            |  |                 |
| SEND ALL CORRESPONDENCE TO:<br>Philip S. Johnson, Esq.<br>Johnson & Johnson<br>One Johnson & Johnson Plaza<br>New Brunswick, NJ 08933-7003<br>USA  |              |   |            | /Laura A. Donnelly/<br><br>Signature<br>Name: Laura A. Donnelly<br>Reg. No. 38,435<br>Attorney for Applicant<br>Dated: February 28, 2006 |                 |

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|  |              |   |            |  |                 |
|--|--------------|---|------------|--|-----------------|
| U.S. APPLICATION NO. (if known, see 37 CFR 1.5)<br><b>10/1570228</b>   |              | INTERNATIONAL APPLICATION NO.<br>PCT/EP2004/052028                            |            | ATTORNEY'S DOCKET NUMBER<br>TIP-0058-USPCT   |                 |
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| TOTAL FEES ENCLOSED =  |              |   |            | \$ 80.00   |                 |
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| SEND ALL CORRESPONDENCE TO:<br>Philip S. Johnson, Esq.<br>Johnson & Johnson<br>One Johnson & Johnson Plaza<br>New Brunswick, NJ 08933-7003<br>USA  |              |   |            | /Laura A. Donnelly/<br><br>Signature<br>Name: Laura A. Donnelly<br>Reg. No. 38,435<br>Attorney for Applicant<br>Dated: February 28, 2006 |                 |

10/570228

IAP6 Rec'd PCT/PTO 28 FEB 2006

TIP-0058-USPCT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Paul Stoffels

For: COMBINATIONS OF A PYRIMIDINE CONTAINING NNRTI WITH  
RT INHIBITORS

Express Mail Certificate

"Express Mail" mailing number: EL 960331928 US

Date of Deposit: February 28, 2006

I hereby certify that this entry into the National Phase pursuant to 35 USC 371 contains complete application:

|   |                              |
|---|------------------------------|
| Express Mail Certificate  | (1 page)                     |
| Return Receipt Postcard   | (1 page)                     |
| PCT FORM 1390 Transmittal                                       | (2 pages & 2 copies of same) |
| Copy of International Application as filed                      | (31 pages)                   |
| Executed Power of Attorney (1)                                  | (1 page)                     |
| Executed Assignments (2) with<br>Cover Sheets                   | (5 pages)                    |
| Certificate Under 37 CFR 3.73(b)                                | (1 page –double-sided)       |
| Information Disclosure Statement and<br>Form 1449 and MPEP 609D | (6 pages)                    |
| Written Opinion of the ISA                                      | (6 pages)                    |
| PCT Declaration of Inventorship                                 | (2 pages)                    |
| PCT Request   | (5 pages)                    |
| Preliminary Amendment   | (7 pages)                    |
| Copy of WO 2005/021001 A1 (34 pages including drawings and ISR) |                              |

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee; service under 37 CFR 1.10 on the date indicated above is addressed to the Mail Stop: Patent Application, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Laurie A. Phillips

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/Laurie A. Phillips/

(Signature of person mailing paper or fee)